510(k) Summary

MAY 1 2 2014

for

Ross Ru Skin Discontinuities

1. Submission Sponsor

BioTD, S.A.
Edificio 26 Condominio Industrial San Jose de Ulloa
Heredia
Costa Rica
Phone: 1 501 868 8300
Fax: N/A
Contact: Robin Wiscovitch, Ph.D, Chief Executive Officer

2. Submission Correspondent

Emergo Group
816 Congress Ave, Suite 1400
Austin, TX 78701
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Contact: Richard Gillis, PhD, Senior Consultant
Email: project.management@emergogroup.com

3. Date Prepared

May 8, 2014

4. Device Identification

Trade/Proprietary Name:	Ross Ru Skin Discontinuities
Common/Usual Name:	Wound gel
Classification Name:	Dressing, Wound, Drug
Classification Regulation:	Not specified
Product Code:	FRO
Device Class:	Unclassified (Pre-Amendment)
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

ASAP Wound Gel (K082333)

6. Device Description

Ross Ru is a wound dressing gel that helps maintain a moist wound environment that is conducive to healing, by either absorbing or donating the moisture and wound exudates and may inhibit the growth of microorganisms within the dressing. Ross Ru Skin

Discontinuities is supplied in a collapsible low density polyethylene tube sealed at one end and fitted with a dispensing orifice at the other end accessible by the removal of its screw cap.

7. Indication for Use Statement

An over-the-counter (OTC) product for topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations.

8. Substantial Equivalence Discussion

The following table compares the Ross Ru Skin Discontinuities to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**BioTD, S.A.**	**American Biotech Labs, LLC**	**SIGNIFICANT DIFFERENCES**
Trade Name	Ross Ru Skin Discontinuities	ASAP Wound Gel	
510(k) Number	Not assigned	K082333	N/A
Product Code	FRO	FRO	Same
Regulation Number	Not specified	Not specified	Same
Regulation Name	Dressing, Wound, Drug	Dressing, Wound, Drug	Same
Indications for Use	An over-the-counter (OTC) product for topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations.	For the topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations	Same
Material	Deionized water, silver nanoparticles, Carbopol, sodium hydroxide	Purified water, nano-silver at 0.1 micron, TEA, carbopol, propylene glycol	Similar; the differences between them are the neutralizing agents to facilitate carbopol gelling. Per the manufacturer's instructions, carbopol requires a neutralizing agent for gelling. TEA or sodium hydroxide can be used, among others.
Sterile	Non-sterile	Non-sterile	Same
Single-Use	Yes	Yes	Same
Shelf Life	3 years	N/A	NA; predicate device shelf life is not available
Complies with ISO 10993-1	Yes	Yes	Same
Complies with Antimicrobial Test <USP 51>	Yes	Yes	Same

9. Non-Clinical Performance Data

The following testing has been performed to support substantial equivalence:

- Cytotoxicity Assay (ISO 10993-5:2009). The test product extract showed no cytotoxic potential.
- Sensitization Test (ISO 10993-1:2009, -10:2010, -12:2012). The test substance was non-sensitizing.
- Irritation Test (ISO 10993-10:2010). Ross Ru Skin Discontinuities was determined to be non-irritating.
- Antimicrobial Effectiveness Test <USP 51> –
  Ross Ru Skin Discontinuities was evaluated for preservative activity in compliance with USP 51 Antimicrobial Effectiveness Test, designed to test efficacy of preservatives. Exposure to Ross Ru Discontinuities caused a significant reduction in *Pseudomonas aeruginosa*, *E. coli*, *Staphylococcus aureus*, *Candida albicans*, and *Aspergillus niger*.

As part of demonstrating safety and effectiveness of Ross Ru Skin Discontinuities and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, BioTD, S.A. completed a number of tests. The Ross Ru Skin Discontinuities meets all the requirements for overall design and biocompatibility, which confirm that the outputs meets the design inputs and specifications. The Ross Ru Skin Discontinuities passed all testing stated above as shown by the acceptable results obtained.

The Ross Ru Skin Discontinuities complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the Ross Ru Skin Discontinuities and the predicate device do not raise any questions regarding its safety and effectiveness. The Ross Ru Skin Discontinuities, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 12, 2014

BioTD, S.A.
% Richard Gillis, Ph.D.
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K131176
Trade/Device Name: Ross Ru Skin Discontinuities
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 28, 2014
Received: March 31, 2014

Dear Dr. Gillis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131176

Device Name
Ross Ru Skin Discontinuities

Indications for Use *(Describe)*
An over-the-counter (OTC) product for topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joseph Nielsen -S
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